K076447

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510(k) Summary

AUG 2 8 2008

Manufacturer:
Tri-State Hospital Supply Corporation
301 Catrell Drive
Howell, MI 48843

Contact:
Mr. Matthew K. Price
Director of Quality Assurance & Regulatory Affairs
Tri-State Hospital Supply Corporation
301 Catrell Drive
Howell, MI 48843
Phone: (517) 546-1135
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Date Summary Prepared: February 15, 2008

Proprietary Name: Centurion® Protective Restraint
Common Name of Device: Protective Restraint

Classification Name: Restraint, Protective
Device Classification: Class I
Regulation: 880.6760
Product Code: FMQ
Panel: General Hospital

Predicate SE Device(s):

This product is similar in design, composition, function, and method of use to the Posey Company Pediatric Limb Holder (K963439).

Description:

The Centurion® Protective Restraint is a device comprised of hook and loop material, 100% nylon fabric with polyester foam core, and nylon tricot backing.

Intended Use:

The Centurion® protective restraint is a device, including a wristlet, anklet, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.

This device is intended for use on neonatal/newborn patients by or on the order of a physician in a hospital or clinic setting.

The device is contraindicated for use on patients with dislocations, fractures, open wounds on the affected limb, or if I.V. site can be compromised.

Summary of Technological Characteristics between Subject and Predicate Device:

The predicate device (K963439) provides the same functions, characteristics described herein for the device. Although there are some dimensional differences between the predicate device and the Centurion® Protective Restraint, the difference is minor and raises no new questions of safety or effectiveness.

Summary of Testing:

Comparative bench performance testing was performed to evaluate the physical integrity and performance of the device and its predicate. The results demonstrate that the device satisfies all performance, physical, and functional requirements and the device is as safe, as effective, and performs as well as the predicate device. No new issues of safety or efficacy were found.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 - 2008

Mr. Matthew K. Price
Director of Quality Assurance & Regulatory Affairs
Tri-State Hospital Supply Corporation
301 Catrell Drive
Howell, Michigan 48843

Re: K080448
Trade/Device Name: Centurion® Protective Restraint
Regulation Number: 21 CFR 880.6760
Regulation Name: Protective Restraint
Regulatory Class: I
Product Code: FMQ
Dated: August 20, 2008
Received: August 21, 2008

Dear Mr. Price:

This letter corrects our substantially equivalent letter of August 28, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K080448

Device Name: Centurion® Protective Restraint

Indications for Use:
The Centurion® Protective Restraint is a device, including a wristlet, anklet, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.

This device is intended for use on neonatal/newborn patients by or on the order of a physician in a hospital or clinic setting.

Contraindications:

The device is contraindicated for use on patients with dislocations, fractures, open wounds on the affected limb, or if I.V. site can be compromised.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080448